U.S. Department of Justice

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April 26, 2019

Melissa Bayer Tearney
Choate Hall & Stewart LLP
Two International Place
Boston, MA 02110

Re: United States v. ACell, Inc.,
Criminal No. ELH-19- 0282(D.MD)

Dear Counsel:

This letter confirms the plea agreement (this "Agreement") that has been offered to your client, ACell, Inc. (hereinafter "Defendant"), by the United States Attorney's Office for the District of Maryland ("this Office") and the United States Department of Justice Consumer Protection Branch (hereinafter jointly "the United States"). If the Defendant accepts this offer, please have the Defendant execute it in the spaces provided below. **The plea agreement is entered into and will be submitted to the Court pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C).** If this offer has not been accepted within 10 calendar days of the date of this Agreement, it will be deemed withdrawn. The terms of the Agreement are as follows:

Offense of Conviction

1. The Defendant agrees to plead guilty to Count One of an Information to be filed against the Defendant, which will charge the Defendant with Failure and Refusal to Report Medical Device Removal, in violation of 21 U.S.C. §§ 331(q)(1)(B), 360i(g), and 333(a)(1), a Class A Misdemeanor. The Defendant admits that the Defendant is, in fact, guilty of the offense and will so advise the Court.

Elements of the Offense

2. The elements of the offense to which the Defendant has agreed to plead guilty, and which the United States would prove if the case went to trial, are as follows: That on or about the time alleged in the Information, in the District of Maryland, the Defendant (1) manufactured a device under the Federal Food, Drug and Cosmetic Act, to wit, MicroMatrix Powder Wound Dressing; (2) removed the device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection; (3) undertook the removal of the

device to reduce a risk to health posed by the device; and (4) failed to report removal of the device to the United States Food and Drug Administration.

Penalties

3. The maximum penalties provided by statute for the offense to which the Defendant is pleading guilty are as follows:

Count	Statutes	Minimum Prison	Maximum Prison	Maximum Fine	Special Assessment
1	21 U.S.C. §§ 331(q)(1)(B), 360i(g), 333(a)(1)	N/A	5 years' probation, 18 U.S.C. § 3561(c)(2)	$200,000.00 or not more than the greater of twice the gross gain or twice the gross loss relating to the offense, 18 U.S.C. § 3571(c)(5), (d).	$125.00, 18 U.S.C. § 3013(a)(1)(B)(iii)

a. Restitution: The Court may order the Defendant to pay restitution pursuant to 18 U.S.C. §§ 3663, 3663A, and 3664.

b. Payment: If a fine or restitution is imposed, it shall be payable immediately, unless the Court orders otherwise under 18 U.S.C. § 3572(d). The Defendant may be required to pay interest if the fine is not paid when due.

c. Forfeiture: The Court may enter an order of forfeiture of assets directly traceable to the offense, substitute assets, and/or a money judgment equal to the value of the property subject to forfeiture.

d. Collection of Debts: If the Court imposes a fine or restitution, this Office's Financial Litigation Unit will be responsible for collecting the debt. If the Court establishes a schedule of payments, the Defendant agrees that: (1) the full amount of the fine or restitution is nonetheless due and owing immediately; (2) the schedule of payments is merely a minimum schedule of payments and not the only method, nor a limitation on the methods, available to the United States to enforce the judgment; and (3) the United States may fully employ all powers to collect on the total amount of the debt as provided by law. Until the debt is paid, the Defendant agrees to disclose all assets in which the Defendant has any interest or over which the Defendant exercises direct or indirect control. Until the money judgment is satisfied, the Defendant authorizes the United States to evaluate the Defendant's ability to pay, and to request and review the Defendant's federal and state income tax returns. The Defendant agrees to complete and sign a copy of IRS Form 8821 (relating to the voluntary disclosure of federal tax return information) and a financial statement in a form provided by the United States.

Waiver of Rights and Defenses

4. The Defendant understands that by entering into this Agreement, the Defendant surrenders certain rights as outlined below:

a. If the Defendant had pled not guilty and persisted in that plea, the Defendant would have had the right to a speedy jury trial with the close assistance of competent counsel. A judge, without a jury, could conduct the trial if the Defendant, the United States, and the Court all agreed.

b. If the Defendant elected a jury trial, the jury would be composed of twelve individuals selected from the community. Counsel and the Defendant would have the opportunity to challenge prospective jurors who demonstrated bias or who were otherwise unqualified, and would have the opportunity to strike a certain number of jurors peremptorily. All twelve jurors would have to agree unanimously before the Defendant could be found guilty of any count. The jury would be instructed that the Defendant was presumed to be innocent, and that presumption could be overcome only by proof beyond a reasonable doubt.

c. If the Defendant went to trial, the government would have the burden of proving the Defendant guilty beyond a reasonable doubt. The Defendant would have the right to confront and cross-examine the Government's witnesses. The Defendant would not have to present any defense witnesses or evidence whatsoever. If the Defendant wanted to call witnesses in its defense, the Defendant would have the subpoena power of the Court to compel the witnesses to attend.

d. The Defendant would have the right to testify in the Defendant's own defense if the Defendant so chose, and the Defendant would have the right to refuse to testify. If the Defendant chose not to testify, the Court could instruct the jury that they could not draw any adverse inference from the Defendant's decision not to testify.

e. If the Defendant were found guilty after a trial, the Defendant would have the right to appeal the verdict and the Court's pretrial and trial decisions on the admissibility of evidence to see if any errors were committed which would require a new trial or dismissal of the charges. By pleading guilty, the Defendant knowingly gives up the right to appeal the verdict and the Court's decisions.

f. By pleading guilty, the Defendant will be giving up these rights, except the right, under the limited circumstances set forth in the "Waiver of Appeal" paragraph below, to appeal the sentence. By pleading guilty, the Defendant understands that the Defendant may have to answer the Court's questions both about the rights being given up and about the facts of the case. Any statements that the Defendant makes during such a hearing would not be admissible against the Defendant during a trial except in a criminal proceeding for perjury or false statement.

g. If the Court accepts the Defendant's plea of guilty, the Defendant will be giving up the right to file and have the Court rule on pretrial motions, and there will be no further trial or proceeding of any kind in the above-referenced criminal case, and the Court will find the Defendant guilty.

h. Should the Defendant move to withdraw or otherwise challenge the Defendant's guilty plea at any time, should the Defendant breach this Agreement, or should the Court reject the Defendant's guilty plea for whatever reason, the Defendant agrees to waive any defenses based upon the statute of limitations, any protection against pre-indictment delay, and the Speedy Trial Act with respect to any and all charges that could have been timely brought or pursued as of the date of this Agreement.

Advisory Sentencing Guidelines Apply

5. The Defendant understands that the Court will determine a sentencing guideline range for this case (henceforth the "advisory guidelines range") pursuant to the Sentencing Reform Act of 1984 at 18 U.S.C. §§ 3551-3742 (excepting 18 U.S.C. §§ 3553(b)(1) and 3742(e)) and 28 U.S.C. §§ 991 through 998. The Defendant further understands that the Court will impose a sentence pursuant to the Sentencing Reform Act, as excised, and must take into account the advisory guidelines range in establishing a reasonable sentence.

Factual and Advisory Guidelines Stipulation

6. The United States and the Defendant stipulate and agree to the Statement of Facts set forth in Attachment A, which is incorporated by reference herein, and to the following sentencing guidelines.

a. The United States and the Defendant further agree that the applicable base offense level is 6 pursuant to United States Sentencing Guidelines ("U.S.S.G.") §§ 2N2.1 and 2X5.2.

b. The United States and the Defendant further agree that the base fine is $31,000,000, pursuant to U.S.S.G. § 8C2.4(a)(2), because this is the pecuniary gain to the organization from the offense.

c. The United States and the Defendant further agree that, pursuant to U.S.S.G. § 8C2.5, the culpability score is 6, which is determined as follows:

i. The base culpability score is 5, pursuant to U.S.S.G. § 8C2.5(a);

ii. The culpability score is increased by 3 points, pursuant to U.S.S.G. § 8C2.5(b)(3)(A), because the Defendant had 200 or more employees and individuals within high-level personnel of the organization participated in, condoned, or were willfully ignorant of the offense, and tolerance of the offense by substantial authority personnel was pervasive throughout the organization;

iii. The culpability score is decreased by 2 points, pursuant to U.S.S.G. § 8C2.5(g)(2), because the Defendant fully cooperated in the investigation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct.

d. The United States and the Defendant further agree that the multiplier range associated with a culpability score of 6 is 1.20 – 2.40, pursuant to U.S.S.G. § 8C2.6.

e. The United States and the Defendant further agree that the advisory guideline fine range is $37,200,000 to $74,400,000, pursuant to U.S.S.G. § 8.C2.7.

f. The United States and the Defendant further agree that the maximum fine is $62,000,000, pursuant to 18 U.S.C § 3571(d).

7. The United States and the Defendant further agree that while the fine provisions of the U.S.S.G. do not apply to organizational defendants that are convicted of misdemeanor violations of the Federal Food, Drug, and Cosmetic Act, U.S.S.G. § 8C2.1, the agreed disposition is consistent with the U.S.S.G. and takes into account the Defendant's conduct under 18 U.S.C. §§ 3553 and 3572 and U.S.S.G. § 8C2.10.

Rule 11(c)(1)(C) Plea

8. The parties stipulate and agree pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C) that a criminal fine in the amount of $3,000,000.00 is the appropriate disposition of this case taking into consideration the nature and circumstances of the offense, the Defendant's criminal history, and all of the other factors set forth in 18 U.S.C. § 3553(a). The parties further stipulate and agree to payment of the fine as follows:

a. $500,000.00 to be paid within three business days of when the judgment is issued and the remaining $2,500,000.00 to be paid in twenty quarterly installments over five years, with the first quarterly payment to occur within ninety calendar days of the date of when the judgment is issued and the remaining nineteen payments due every ninety days thereafter. Payment of interest from the first payment date on the unpaid principal balance at the rate of 2.875 percent per annum is payable with each quarterly installment of principal, as follows:

Quarter	Payment	2.8750% Interest	Principal	Balance
				$3,000,000.00
Initial Payment	$500,000.00	$0.00	$500,000.00	$2,500,000.00
Quarter 1	$119,118.75	$17,968.75	$101,150.00	$2,398,850.00
Quarter 2	$118,391.73	$17,241.73	$101,150.00	$2,297,700.00
Quarter 3	$117,664.72	$16,514.72	$101,150.00	$2,196,550.00
Quarter 4	$116,937.70	$15,787.70	$101,150.00	$2,095,400.00
Quarter 5	$146,004.22	$15,060.69	$130,943.53	$1,964,456.47
Quarter 6	$145,063.06	$14,119.53	$130,943.53	$1,833,512.93
Quarter 7	$144,121.90	$13,178.37	$130,943.53	$1,702,569.40
Quarter 8	$143,180.75	$12,237.22	$130,943.53	$1,571,625.86
Quarter 9	$142,239.59	$11,296.06	$130,943.53	$1,440,682.33
Quarter 10	$141,298.43	$10,354.90	$130,943.53	$1,309,738.80

Quarter 11	$140,357.28	$9,413.75	$130,943.53	$1,178,795.26
Quarter 12	$139,416.12	$8,472.59	$130,943.53	$1,047,851.73
Quarter 13	$138,474.96	$7,531.43	$130,943.53	$916,908.20
Quarter 14	$137,533.81	$6,590.28	$130,943.53	$785,964.66
Quarter 15	$136,592.65	$5,649.12	$130,943.53	$655,021.13
Quarter 16	$135,651.49	$4,707.96	$130,943.53	$524,077.59
Quarter 17	$134,710.34	$3,766.81	$130,943.53	$393,134.06
Quarter 18	$133,769.18	$2,825.65	$130,943.53	$262,190.53
Quarter 19	$132,828.02	$1,884.49	$130,943.53	$131,246.99
Quarter 20	$132,190.33	$943.34	$131,246.99	$0.00
	$3,195,545.09	**$195,545.09**	**$3,000,000.00**	

b. The parties stipulate and agree that the fine in subparagraph (a) above is less than the advisory guidelines fine range but is nevertheless a reasonable sentence, taking into consideration the factors set forth in 18 U.S.C. §§ 3553(a) and 3572, including that the Defendant has asserted the inability to pay the minimum advisory guidelines fine without substantially jeopardizing its continued existence. Based on a review of the Defendant's financial statements and tax returns by the United States, pursuant to U.S.S.G. § 8C3.3(b), there is a basis for the imposition of a fine below that otherwise recommended by U.S.S.G. § 8C2.7. The United States agrees that the Defendant is not able to pay and, even with the use of a reasonable installment schedule, is not likely to become able to pay the minimum fine required by U.S.S.G. § 8C2.7(a).

c. The above-referenced agreed-upon sentence is contingent upon the execution of a Civil Settlement Agreement ("Settlement Agreement") between the Defendant and the United States, which is being signed contemporaneously with this Agreement and is appended as Attachment B. The terms of the Settlement Agreement require the Defendant to pay the United States and the Medicaid Participating States collectively $12,000,000.00 ("Settlement Amount"), of which $11,830,020.00 is the federal portion ("Federal Settlement Amount"). The initial payment of Five-Hundred Thousand Dollars ($500,000.00), plus accrued interest at the rate of 2.875 percent accrued since September 1, 2018, shall be paid to the United States no later than seven (7) days after (i) the Settlement Agreement is fully executed by the parties and delivered to the Defendant's attorneys, or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea as to the Defendant and imposes the agreed-upon sentence, whichever occurs later. Thereafter, the balance of the Federal Settlement Amount (plus accrued interest at the rate of 2.875 percent) shall be payable to the United States pursuant to instructions from the Civil Division of the United States Department of Justice, in twenty quarterly installments over five years, with the first quarterly payment to occur within ninety calendar days of the date of the initial payment. $169,980.00 ("State Settlement Amount") plus accrued interest shall be payable to the Medicaid Participating States pursuant to instructions from the Medicaid Participating States.

d. The payments set forth above in Paragraphs 8.a. and 8.c. are subject to acceleration if a sale of the Defendant occurs before the expiration of the payment term.

e. The parties agree that the Settlement Agreement in United States of America rel. John Murtaugh v. ACell, Inc., Civil No. ELH-13-1820 (D. Md.) and United States of America rel. Ali Mahdavi v. ACell, Inc., et al., recompenses the Medicare Trust Fund for false

claims that the Defendant caused to be submitted pursuant to conduct described in the Settlement Agreement.

f. The parties agree that restitution is not required or administratively feasible in this case. The statutory basis for ACell's guilty plea is the Federal Food, Drug, and Cosmetic Act, for Failure and Refusal to Report Medical Device Removal, under 21 U.S.C. §§ 331(q)(1)(B), 360i(g), and 333(a)(1). No statutory basis exists for an order of restitution for that offense under 18 U.S.C. §§ 3663(a)(1)(A) or 3663A(c)(1). The parties also are unaware of any persons "directly and proximately harmed as a result of the commission of an offense for which restitution may be ordered" or "directly and proximately harmed as a result of the commission of a Federal offense" as harm reported from the use of ACell's devices has not been established as directly and proximately traceable to the offense conduct for which ACell is pleading guilty. 18 U.S.C. §§ 3663(a)(2), 3663A(a)(2), 3771(e)(2). In re: Jane Doe, 264 Fed.Appx. 260, 263 (2007), citing United States v. Blake, 81 F.3d 498, 506-07 (4th Cir. 1996); United States v. Guidant LLC, 708 F.Supp.2d 903, 911-15 (D. Minn. 2010). Furthermore, the parties agree that attempting to fashion an order to provide restitution to any such possible persons would result in complication and prolongation of the sentencing process that would outweigh the need to provide restitution to any such possible persons. 18 U.S.C. § 3663(a)(1)(B)(ii).

g. The Defendant agrees to establish and maintain a Compliance and Ethics Program to govern its business operations pursuant to the provisions set forth in Attachment C of this Agreement.

h. This Agreement does not affect the Court's discretion to impose any lawful term of probation or to set any lawful conditions of probation. 18 U.S.C. § 3561(a); U.S.S.G. § 8D.1.

9. In the event that the Court rejects this plea agreement, except under the circumstances noted below, either party may elect to declare the Agreement null and void. Should the Defendant so elect, it will be afforded the opportunity to withdraw from the plea pursuant to the provisions of Federal Rule of Criminal Procedure 11(c)(5).

10. The Defendant may seek sentencing by the Court immediately following the Rule 11 plea hearing. The United States will not object to the Court proceeding to sentencing the Defendant immediately following the Rule 11 plea hearing or in the absence of a Presentence Report if, in advance of the Rule 11 plea hearing, the Defendant requests immediate sentencing to be held on the same day as the Rule 11 plea hearing. The Defendant understands that the decision whether to proceed immediately with sentencing following the Rule 11 plea hearing, and to do so without a Presentence Report, is exclusively that of the Court.

Obligations of the Parties

11. At the time of sentencing, the United States and the Defendant will jointly request that the Court accept the stipulated sentence of a fine in the amount of $3,000,000.00, as set forth above. The United States and the Defendant reserve the right to advocate for a reasonable period of probation considering any appropriate factors under 18 U.S.C. § 3553(a). The United States and the Defendant reserve the right to bring to the Court's attention all information with respect to

the Defendant's background, character, and conduct that the United States or the Defendant deem relevant to sentencing, including the conduct that is the subject of the Information and the Statement of Facts.

Defendant's Obligations

12. a. Between now and the date of the sentencing, the Defendant will not engage in conduct that constitutes obstruction of justice under U.S.S.G. § 3C1.1; will not violate any federal, state, or local law; will acknowledge guilt to the Court and the probation officer; will be truthful in any statement to the Court, the United States, law enforcement agents, and probation officers; will cooperate in the preparation of the presentence report; and will not move to withdraw from the plea of guilty or from this Agreement. The Defendant will abide by all terms and obligations of this Agreement.

b. If the Defendant engages in conduct prior to sentencing that violates the above paragraph of this Agreement, and the Court finds a violation by a preponderance of the evidence, then: (i) the United States will be free from its obligations under this Agreement; (ii) the United States may make sentencing arguments and recommendations different from those set out in this Agreement, even if the Agreement was reached pursuant to Rule 11(c)(1)(C); and (iii) in any criminal or civil proceeding, the United States will be free to use against the Defendant all statements made by the Defendant and any of the information or materials provided by the Defendant, including statements, information, and materials provided pursuant to this Agreement, and statements made during proceedings before the Court pursuant to Rule 11 of the Federal Rules of Criminal Procedure. A determination that the United States is released from its obligations under this Agreement will not permit the Defendant to withdraw the guilty plea. The Defendant acknowledges that the Defendant may not withdraw the Defendant's guilty plea—even if made pursuant to Rule 11(c)(1)(C)—if the Court finds that the Defendant breached the Agreement. In that event, neither the Court nor the United States will be bound by the specific sentence or sentencing range agreed and stipulated to herein pursuant to Rule 11(c)(1)(C).

c. The Defendant acknowledges that its prior, ongoing, and future cooperation is an important and a material factor underlying the United States' decision to enter into this Agreement. The Defendant agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities involving the subject matters identified in Paragraph 15. Upon reasonable notice, the Defendant shall encourage, and agrees will not impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. The Defendant further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation that it has undertaken, or that has been performed by another on its behalf, involving any of the subject matters investigated by the United States in connection with the conduct encompassed by this Agreement.

d. The Defendant's obligations to cooperate do not extend to or include privileged information, except to the extent that the Defendant knowingly and voluntarily elects or has elected previously to waive privilege.

13. The United States expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of the Defendant, in connection with the conduct encompassed by this Agreement, within the scope of the investigation, or known to the United States.

14. The United States may, at its sole option, be released from its commitments under this Agreement if at any time after the Defendant's execution of this Agreement, the Defendant fails to abide by all terms and obligations of the Agreement, or if the plea entered pursuant to this Agreement is vacated, reversed, or set aside for any reason.

Agreement Not to Further Prosecute Other Offenses the Defendant May Have Committed

15. Under Fed. R. Crim. P. 11(c)(1)(A), the United States agrees that, other than the charge in the Information, it shall not further prosecute the Defendant for any additional federal criminal charges or charges under the Food Drug and Cosmetic Act with respect to the conduct between the years 2011 and 2017 that falls within the scope of (1) the Information to which the Defendant pleads guilty; (2) the Statement of Facts, Attachment A hereto; or (3) the Settlement Agreement, Attachment B hereto. The United States does not decline criminal prosecution of the Defendant for any other conduct beyond that set forth above. This declination is expressly contingent upon (1) the guilty plea of the Defendant to the Information being accepted by the Court and not withdrawn or otherwise challenged; and (2) the Defendant's performance of all of its obligations as set forth in this Agreement and the Civil Settlement Agreement. If the Defendant's guilty plea is not accepted by the Court or is withdrawn for any reason, or the Defendant should fail to perform any obligation under this Agreement or the Civil Settlement Agreement, this declination of prosecution shall be null and void.

Waiver of Appeal

16. In exchange for the concessions made by the United States and the Defendant in this Agreement, the United States and the Defendant waive their rights to appeal as follows:

a. The Defendant knowingly waives all right, pursuant to 28 U.S.C. § 1291 or any other statute or constitutional provision, to appeal the Defendant's conviction on any ground whatsoever. This includes a waiver of all right to appeal the Defendant's conviction on the ground the statutes to which the Defendant is pleading guilty are unconstitutional, or on the ground that the admitted conduct does not fall within the scope of the statutes, to the extent that such challenges legally can be waived.

b. The Defendant and the United States knowingly and expressly waive all rights conferred by 18 U.S.C. § 3742 to appeal whatever sentence is imposed (including any fine, term of probation, or order of restitution) for any reason (including the establishment of the advisory sentencing guidelines range, the weighing of the sentencing factors, and any constitutional challenges to the calculation and imposition of any fine, order of forfeiture, order of restitution, and term or condition of probation), except as follows:

i. The Defendant reserves the right to appeal any sentence that exceeds the statutory maximum; and

ii. The United States reserves the right to appeal any sentence below a statutory minimum.

c. The Defendant waives any and all rights under the Freedom of Information Act relating to the investigation and prosecution of the above-captioned matter and agrees not to file any request for documents from the United States or any investigating agency.

Tax Liability

17. The Defendant understands that this Agreement does not resolve any civil tax liability that the Defendant may have, and that this Agreement is with the United States Attorney's Office and the United States Department of Justice Consumer Protection Branch, not with the Internal Revenue Service. The Internal Revenue Service is not a party to this Agreement and remains free to pursue any and all lawful remedies it may have.

Entire Agreement

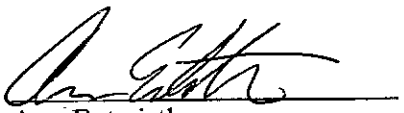
18. This letter constitutes the complete plea agreement in this case. This letter supersedes any prior understandings, promises, or conditions between the United States and the Defendant. There are no other agreements, promises, undertakings, or understandings between the Defendant and the United States other than those set forth in this letter. No changes to this Agreement will be effective unless in writing, signed by all parties, and approved by the Court.

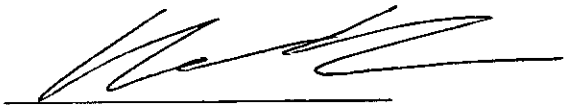
If Defendant fully accepts each and every term and condition of this Agreement, please sign and have the Defendant sign the original and return it to me promptly.

Very truly yours,

Robert K. Hur
United States Attorney

By: 
Roann Nichols
Assistant United States Attorney


Ann Entwistle
Trial Attorney


Clint Narver
Trial Attorney

U.S. Department of Justice
Consumer Protection Branch

By virtue of Unanimous Consent adopted by the Board of Directors of ACell, Inc. (appended to this Agreement as Attachment D), I have been authorized, empowered, and directed to represent ACell, Inc. before the Court in order to make statements and confirmations in accordance with this Agreement, including entering a guilty plea on behalf of the Defendant. I have read this Agreement, and carefully reviewed every part of it with ACell's attorney. I understand it and I voluntarily agree to it. Specifically, I have reviewed the Factual and Advisory Guidelines Stipulation with the Defendant's attorney and I do not wish to change any part of it. ACell, Inc. is completely satisfied with the representation of its attorney.

5/9/19
Date

Patrick McBrayer
President and Chief Executive Officer
Defendant ACell, Inc.

I am the Defendant's attorney. I have carefully reviewed every part of this Agreement with the Defendant and its designated representative. The Defendant advises me that the Defendant understands and accepts its terms. To my knowledge, the Defendant's decision to enter into this Agreement is an informed and voluntary one.

5/9/19
Date

Melissa Bayer Tearney
Melissa Bayer Tearney, Esq.

ATTACHMENT A

STATEMENT OF FACTS – ACELL, INC.

The undersigned parties hereby stipulate and agree that if this matter had gone to trial, the United States would have proven the following facts beyond a reasonable doubt. The undersigned parties also stipulate and agree that the following facts do not encompass all of the evidence which would have been presented had this matter gone to trial:

A. Defendant ACELL, Inc.

At times material to this case, defendant **ACELL, INC. ("ACELL")** was a business corporation organized under the laws of the State of Delaware with its principal place of business in Columbia, Maryland.

Defendant **ACELL** engaged in the development, manufacture, processing, packaging, sale, marketing, and interstate distribution of certain medical devices intended for human use throughout the United States, including the District of Maryland.

B. The FDA and FDCA

The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA") by assuring, among other things, that medical devices intended for use in the treatment of human beings were safe and effective for their intended uses. Pursuant to its statutory mandate, the FDA regulated the manufacture, processing, packing, labeling, and shipment in interstate commerce of medical devices.

Under the FDCA, the term "device" included "an instrument, apparatus, . . . implant . . . or other similar or related article . . . which is . . . intended for use in . . . the . . . treatment or prevention of disease, in man . . . which does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

Under the FDCA, the term "labeling" was defined as all labels and other printed or graphic matter upon any article, including medical devices, or any of its containers or wrappers, or accompanying such articles. 21 U.S.C. § 321(m).

The FDCA and its implementing regulations prohibited manufacturers from distributing in interstate commerce any medical device unless the FDA had granted marketing authorization for the device or the device was covered by an exemption not

applicable here. There generally were two ways for a manufacturer to obtain FDA marketing authorization for a medical device.

The first way for a manufacturer to obtain authorization to distribute a medical device lawfully was by receiving FDA approval of the manufacturer's application for pre-market approval of the device ("PMA approval"). The FDA would not grant PMA approval unless the information in the PMA application provided the FDA with reasonable assurance that the device was safe and effective for its intended use, as reflected in its FDA-approved labeling.

The second way for a manufacturer to obtain authorization to lawfully distribute a medical device was by receiving FDA clearance that the medical device was substantially equivalent to a device that already was legally being marketed, *i.e.*, a "predicate device." This process was referred to as "510(k) clearance." The FDA would grant 510(k) clearance if it determined, among other things, that the device had the same intended use as the predicate device and did not raise new issues of safety or effectiveness.

The PMA approval process often required that manufacturers submit the results of clinical testing on human subjects to the FDA. The 510(k) clearance process did not usually require the submission of such data.

Regardless of the route chosen by a device manufacturer in seeking the FDA's approval to market a medical device, a device manufacturer's application to the FDA was required to contain proposed labeling sufficient to describe the device, its proposed indication for use, and the directions for its proposed indication for use. Any FDA clearance or approval of a device was based on and limited to a specific and defined indication for use. Later, if a device manufacturer wanted to market a device for an expanded or different indication than that approved or cleared by the FDA, the device manufacturer would be required to seek further marketing authorization from the FDA via an additional approval or clearance application.

After receiving approval or clearance to market a medical device, a device manufacturer was required to establish and maintain records, make reports, and provide information to the FDA in order to assure the continued safety and effectiveness of its device. In addition, a device manufacturer was required promptly to report to the FDA certain removals of a medical device from the market.

Specifically, the FDCA and its implementing regulations required medical device manufacturers to submit a written report to the FDA within ten days of initiating any "removal" of a device undertaken to reduce a risk to health posed by the device. 21 U.S.C. § 360i(g); 21 C.F.R. § 806.10. The failure or refusal to make such a report was a prohibited act under the FDCA. 21 U.S.C. § 331(q)(1).

"*Removal* means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection." 21 C.F.R. § 806.2(j) (italics in original).

"*Risk to health* means (1) a reasonable probability that use of, or exposure to the product will cause serious adverse health consequences or death; or (2) that use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious health consequences is remote." 21 C.F.R. § 806.2(k) (italics in original).

The FDCA and its implementing regulations additionally required medical device manufacturers to submit a written report to the FDA within 30 days whenever the manufacturer became aware of information that reasonably suggested that one of its marketed devices may have caused or contributed to a death or serious injury. 21 U.S.C. § 360i(a)(1)(A); 21 C.F.R. 803.10(c)(1).

"'[S]erious injury' [means] an injury that (A) is life threatening, (B) results in permanent impairment of a body function or permanent damage to a body structure, or (C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure." 21 U.S.C. § 360i(a)(2).

C. ACELL's Devices

ACELL manufactured multiple medical devices that were derived from porcine urinary bladder material, including devices that were approved for internal surgical implantation and devices that were approved only as topical wound dressings.

In 2004, **ACELL** received clearance for ACell UBM Surgical Mesh ML and MLPlus Sheets for internal use, specifically "implantation to reinforce tissue where weakness exists in urological, gynecological, and gastrointestinal anatomy, including, but not limited to the following procedures: pubourethral support, tissue repair, body wall repair, and esophageal repair." ACell UBM Surgical Mesh ML and MLPlus were marketed under the brand name MatriStem Plastic Surgery Matrix XS (PSMX). PSMX Sheets were sterilized, dried sheets of porcine bladder material. The PSMX Sheets were produced by layering multiple sheets of porcine bladder material atop each other to produce a single, thicker, sheet.

ACELL's Powder Wound Dressing was produced by grinding the bladder sheets into a particulate, and was cleared for "the management of topical wounds." The ground powder was packaged into vials and sold under the name MicroMatrix in quantities ranging from 20 mg to 1,000 mg.

D. The FDA Clearance Process for ACELL's MicroMatrix

On or about March 31, 2006, **ACELL** submitted a 510(k) premarket notification to the FDA requesting approval to market ACell Powder Wound Dressing (which was sold under the name MicroMatrix).

After evaluating **ACELL**'s initial 510(k) submission for MicroMatrix, the FDA expressed concern about **ACELL**'s proposed indication for the device. In a May 19, 2006 letter to **ACELL**, the FDA informed the company that, "[t]he predicate device, K030921, states in the device name 'topical wound dressing.' The subject device does not have any statement regarding topical use. Please include as part of the device name or in the indication for use a [phrase] that states 'for skin surface wounds.' You need to be clear that this device is not intended for internal use; otherwise, this indication would require a premarket application."

In response to the FDA's request, **ACELL** modified MicroMatrix's proposed indication for use statement to include the word "topical," clarifying that the product was intended for topical use only and not intended for internal use.

Upon receipt of **ACELL**'s clarification and representation that the device was intended only for topical use, on or about June 23, 2006, the FDA cleared MicroMatrix via 510(k) number K060888. The FDA clearance letter accompanying 510(k) number K060888 explicitly stated that MicroMatrix was indicated only for "the management of topical wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), and draining wounds."

E. Endotoxin Contamination in ACELL's Products

Endotoxins are complex pyrogenic toxins located in the cell walls of gram-negative bacteria. Endotoxins are released from bacterial cell walls as a byproduct of sterilization processes.

The effects of endotoxin exposure on the human body may include fever, infection, septic shock, and death.

In recognition of these effects, FDA guidance and industry standards set limits capping the acceptable level of endotoxins in a given medical device. These endotoxin limits were based upon the device's intended use. For most medical devices, including devices intended for surgical implantation into the body, FDA guidance and industry standards allowed no more than 20 endotoxin units ("EU") per device. In contrast, FDA guidance and industry standards did not limit the amount of endotoxins that were allowable on medical devices that were intended to be used only as topical wound dressings. The potential harm posed by endotoxin exposure on the external skin surface was comparatively low when compared with the potential harm of internal exposure.

In or about March 2011, **ACELL** performed testing on certain lots of MicroMatrix and discovered endotoxin levels in excess of 20 EU per device. Testing revealed endotoxin levels up to 90 EU per device in the sampled lots. Subsequent testing

in May 2011 revealed endotoxin levels up to 272 EU per device in additional sampled lots.

In or about June 2011, **ACELL** discovered levels of endotoxin on PSMX Sheets in excess of 20 EU per device. **ACELL** calculated that PSMX Sheets could have endotoxin levels up to 128 EU per device, more than six times the limit set by FDA guidance and industry standards for internal use devices. **ACELL** removed the PSMX Sheets from the market after concluding that the elevated levels of endotoxin on PSMX Sheets posed a risk to patient health. **ACELL** also assigned a team of scientists from the Research and Development department ("**ACELL** scientists") to investigate the source of elevated levels of endotoxin contamination and implement solutions.

On July 6, 2011, **ACELL** notified the FDA that it was recalling the PSMX Sheets due to the health risk posed by elevated levels of endotoxin on the devices. Specifically, in its Recall Notification to the FDA, **ACELL** stated that "[e]ndotoxins . . . are substances . . . that, at elevated levels, can cause serious illness which can be fatal" and "[e]levated endotoxin levels may cause fever, serious adverse health consequences or death."

In response to **ACELL**'s Recall Notification, the FDA conducted a Health Hazard Evaluation on the recalled PSMX Sheets and found that, "[t]he immediate and long term health consequences of these defects/malfunctions include fever, patient infection, implant failure requiring surgical intervention, other patient reactions including inflammation, and death."

As part of its efforts to recall the PSMX Sheets, **ACELL** removed approximately 292 devices from its internal warehouse inventory and advised all 24 doctors, who had previously received and implanted the affected devices, that the PSMX Sheets were potentially contaminated by elevated levels of endotoxin. **ACELL** also published a statement on its website notifying the public about the issue.

ACell took no action to recall or remove the MicroMatrix discovered in March 2011 to have elevated levels of endotoxin.

F. ACELL's Development of a Market for Non-FDA Cleared Uses of MicroMatrix

Despite the FDA's warning that **ACELL** would need to submit a PMA if it intended to market its MicroMatrix for internal uses, **ACELL** directed and incentivized its sales force to sell MicroMatrix for a variety of internal uses that the FDA had not cleared.

ACELL senior management directed its sales force to sell MicroMatrix for internal uses, and knew that physicians used MicroMatrix on patients internally, including injecting MicroMatrix into the bodies of patients in applications such as hair

restoration and orthopedic procedures, and implanting MicroMatrix into patients in conjunction with PSMX Sheets.

ACELL used various means to educate its sales force about strategies to market and sell MicroMatrix for internal uses, including through the specific means of a weekly teleconference program called "Bladder Matters." During Bladder Matters calls, featured sales representatives provided advice to **ACELL**'s sales force on how best to maximize product sales, and gave case history presentations demonstrating particularly notable uses of **ACELL** product. As an accompaniment to the case history presentations, **ACELL** distributed PowerPoint presentations depicting how **ACELL** product was utilized in each procedure. These case history presentations at times featured internal usage of MicroMatrix.

ACELL management selected the sales representatives to give case history presentations, and reviewed and vetted the accompanying PowerPoint presentations distributed to the sales force. The Bladder Matters calls described internal MicroMatrix use.

Bladder Matters calls and PowerPoint presentations featured discussions and depictions of the use of MicroMatrix in combination with PSMX Sheets that the FDA had not cleared. PSMX Sheets were indicated for surgical procedures, and doctors used PSMX Sheets in internal surgical procedures. MicroMatrix was indicated for topical use only. Nevertheless, these Bladder Matters calls and PowerPoint presentations described surgical procedures in which MicroMatrix was implanted deeper into the human body than the PSMX Sheets, and the PSMX Sheets were then overlaid atop the MicroMatrix. **ACELL** encouraged its sales force to promote MicroMatrix for this combination use with PSMX Sheets.

ACELL also encouraged the use of MicroMatrix in internal procedures by targeting and hiring certain sales representatives who possessed preexisting relationships with physicians specializing in areas of medicine for which **ACELL** had no FDA-cleared product, including but not limited to dermatological injections.

None of these internal uses were included in the scope of the MicroMatrix 510(k) clearance. In fact, during the clearance process, the FDA had explicitly warned **ACELL** that if it intended to distribute MicroMatrix for such internal uses, **ACELL** was required to submit a PMA application to the FDA.

G. ACELL's Removal of Contaminated MicroMatrix from the Market

In or about January 2012, **ACELL** submitted multiple MicroMatrix devices to a third-party testing company to determine how much endotoxin was present on the powder. The results from the testing affirmed that the elevated levels of endotoxin on MicroMatrix affected a wider range of production lots than those implicated in the 2011 endotoxin testing on the PSMX Sheets. The 2012 test results revealed endotoxin levels above the 20 EU limit in MicroMatrix packaged in 100 mg, 200 mg, 500 mg, and 1,000

mg volumes that spanned a wide range of production lots, and affected over 30,000 devices. The new test results also demonstrated endotoxin levels up to 626 EU per device, over thirty times in excess of the FDA guidance and industry standard limits of 20 EU per device for product used internally.

In or about January 2012, **ACELL** scientists concluded that the MicroMatrix with elevated levels of endotoxin posed a health risk. In a series of meetings, **ACELL** scientific and quality employees presented their findings to **ACELL** senior management and suggested that MicroMatrix be recalled from the market.

ACELL senior management reviewed the findings and recommendations of the investigatory team and concluded that the elevated levels of endotoxin present in MicroMatrix posed a risk to patient health. **ACELL**'s senior management knew that even devices as small as 100 mg and 200 mg from the affected lots of MicroMatrix were contaminated by endotoxin levels above the 20 EU limit and posed a risk to patient health. **ACELL** senior management removed 500 mg and 1,000 mg MicroMatrix devices sourced from the lots contaminated by elevated levels of endotoxin from the market because **ACELL** senior management knew that the 500 mg and 1,000 mg MicroMatrix devices were used internally.

On January 27, 2012, **ACELL** initiated the removal of lots with elevated endotoxin levels by instructing its sales representatives to return all 500 mg and 1,000 mg volumes of MicroMatrix to **ACELL**'s corporate headquarters. **ACELL** instructed its sales force to return product that was held in the sales representatives' personal inventories and product that was held on consignment at the point of use at hospitals and other healthcare facilities.

ACELL did not instruct its sales representatives to return any volumes of MicroMatrix smaller than 500 mg originating from the contaminated lots. Instead, **ACELL** left the smaller volumes of MicroMatrix on the market and made no effort to inform doctors that the smaller volumes of MicroMatrix were contaminated by endotoxin.

Over the following several weeks, **ACELL** sales representatives returned their inventories of 500 mg and 1,000 mg vials of MicroMatrix to **ACELL**'s corporate headquarters. Among other things, these sales representatives removed MicroMatrix sourced from the contaminated lots from its point of use at hospitals and doctors' offices, and shipped it back to **ACELL** corporate headquarters in Maryland.

When the MicroMatrix sourced from the contaminated lots was returned and received at **ACELL**'s corporate headquarters in Maryland, **ACELL** employees placed it in a designated "quarantine area." Subsequently, at the direction of **ACELL** senior management, including **ACELL**'s President, **ACELL** employees removed certain vials of MicroMatrix sourced from the quarantine area and redistributed them to veterinarians. **ACELL** neither informed these veterinarians that the MicroMatrix was from lots with

elevated endotoxin levels nor that the MicroMatrix had been removed from the human medicine market.

Some portion of the MicroMatrix that had been placed into the quarantine area and not redistributed to veterinarians was destroyed.

H. ACELL Senior Management Did Not Disclose the Elevated Levels of Endotoxin in MicroMatrix

ACELL senior management did not inform **ACELL**'s sales force that certain lots of MicroMatrix contained elevated endotoxin levels. Rather, **ACELL** sent sales representatives personalized e-mails that stated, "ACell Corporate is establishing minimum and maximum inventory levels for all ACell field reps, during this time we will be asking you to recycle your current inventory starting with MicroMatrix devices." Each e-mail then listed the quantities of 500 mg and 1,000 mg vials of MicroMatrix that the sales representative had in his or her product inventory, and instructed the representative to return the entire quantity to **ACELL**'s corporate headquarters.

ACELL sales representatives did not know that the MicroMatrix they were instructed to return to company headquarters had elevated endotoxin levels. As a result, some sales representatives delayed returning their inventory. Some sales representatives continued to distribute MicroMatrix from the contaminated lots to doctors after being told to return their inventory. **ACELL** senior management did not inform these sales representatives that the MicroMatrix they had sold and were continuing to sell was from lots with elevated levels of endotoxin.

ACELL also concealed the product contamination and removal from doctors and hospitals. Specifically, **ACELL** did not disclose to doctors and hospitals the fact that the removal of MicroMatrix consignment stock was due to higher levels of endotoxin than was permitted. Among other things, **ACELL**'s management, at the direction of **ACELL**'s President, instructed at least one sales representative to "tell the hospital he is just updating product, that we cycle inventory to prevent any product from sitting on the shelves too long." **ACELL** senior management did not disclose to doctors who continued to buy and use or had used 500 mg and 1,000 mg vials of MicroMatrix the fact that **ACELL** sold and continued to sell product that was subject to a removal action.

ACELL sales representatives continued to distribute 100 mg and 200 mg vials of MicroMatrix that were derived from the contaminated range of production lots. **ACELL** did not disclose to doctors receiving these devices that the lots had elevated levels of endotoxin, and that **ACELL** had conducted a removal of devices of larger vial sizes due to the risk to patient health posed by endotoxins when used internally. **ACELL** sales representatives continued to distribute the 100 mg and 200 mg vials of MicroMatrix despite warnings from **ACELL** scientific and quality employees that these smaller volumes posed the same risk to patient health. Upon being told of the risk to patient health posed by the 100 mg and 200 mg vials of MicroMatrix, **ACELL**'s CEO stated that the devices had "too much street value" to be removed from the market.

ACELL did not disclose important safety information to medical professionals who reported adverse events. **ACELL** received product-related complaints from several medical professionals, including multiple doctors, a veterinarian, and a nurse, all of whom had used MicroMatrix sourced from contaminated lots on patients. These medical professionals reported to **ACELL** adverse events in which patients displayed symptoms consistent with endotoxin exposure, such as fever and inflammation. Various **ACELL** employees, including in some instances **ACELL**'s President, personally discussed the adverse events with these medical professionals, yet **ACELL** did not inform the medical professionals that the MicroMatrix they had used was sourced from lots with elevated levels of endotoxin and the adverse events could potentially be caused by the elevated endotoxin levels present in the MicroMatrix. **ACELL** did not memorialize in company complaint files the fact that the MicroMatrix at issue in these adverse events was sourced from contaminated lots.

Collectively, **ACELL** did not disclose to doctors, veterinarians, nurses, and hospitals important safety information concerning the MicroMatrix that was being used on patients during surgical procedures. By not disclosing this information, **ACELL** prevented these medical professionals and hospitals from making informed decisions regarding their use of **ACELL**'s products.

ACELL did not submit a notification to the FDA informing the agency that it had removed 500 mg and 1,000 mg volumes of MicroMatrix. In connection with the prior July 8, 2011 recall of PSMX Sheets, **ACELL** did submit a removal notification to the FDA. By performing a silent recall of MicroMatrix and not informing the FDA, **ACELL** prevented the FDA from fulfilling its public health responsibility – namely, evaluating whether the actions taken by the company and its management were adequate to protect patient health and safety – and interfered with the FDA's ability to take further actions against **ACELL**'s products.

I. The Insufficiency of ACELL's Complaint Handling Process and the Company's Failure to Submit MDRs to the FDA

As a medical device manufacturer, **ACELL** was required to maintain procedures to receive, review, evaluate, and document complaints concerning **ACELL**'s products. **ACELL** was further required to make a timely report to the FDA whenever **ACELL** became aware that one of its devices may have caused or contributed to a death or serious injury.

Prior to and during the time period of **ACELL**'s removal of medical devices with elevated levels of endotoxin, **ACELL**'s complaint handling procedures were deficient. **ACELL** had no consistent procedures for collecting information regarding complaints and performing thorough and effective complaint investigations. **ACELL** also had no consistent procedures in place for evaluating whether complaints related to events that required reporting to FDA as Medical Device Reports ("MDRs"). Certain adverse events about which **ACELL** was made aware were not documented as complaints, particularly

if those events related to use of **ACELL**'s devices in procedures that had not been cleared by the FDA, such as breast reconstruction.

ACELL employees closed complaints without conducting root cause investigations, and without addressing whether known product deficiencies – such as elevated levels of endotoxin – might have caused or contributed to patient adverse reactions.

In one instance, on October 4, 2011, a doctor complained about fever and the development of abscesses and drainage following the implantation of **ACELL** devices, including Powder Wound Dressing sourced from lots with elevated levels of endotoxin, into a patient. The complaint form documenting **ACELL**'s investigation indicated that **ACELL**'s President contacted the doctor who reported the adverse event, but did not inform the doctor of the elevated levels of endotoxin or discuss with the doctor whether the patient reaction was consistent with exposure to elevated levels of endotoxin. **ACELL** ultimately concluded that, "[f]rom the additional information gathered it is clear that the patient issues were caused by an infection and not product related. No further action is necessary; this does not constitute a reportable event."

In another example, on November 22, 2011, a nurse complained about swelling following the injection of MicroMatrix from one of the lots with elevated endotoxin levels into a patient's forehead. The complaint form documenting **ACELL**'s investigation into the complaint indicated that **ACELL**'s President contacted the nurse who reported the adverse event, but did not disclose that the device used for the injection was sourced from a lot known to be contaminated with high levels of endotoxin and did not discuss the possibility that endotoxin exposure might have caused the patient reaction. **ACELL** ultimately concluded that, "[r]eview of complaint indicates that this does not represent a death or serious injury that should be reported. The product was used in a manner that it is not indicated for and this appears to be primarily an inflammatory response. Close complaint."

In February 2012, a veterinarian contacted **ACELL** regarding a dog and a horse which had both experienced "massive swelling" after receiving injections of MicroMatrix from a 500 mg vial. The device used to treat the dog and the horse was sourced from a lot with elevated levels of endotoxin that was subject to removal from the human market at that time. **ACELL**'s CEO was notified of the existence of this complaint, that the device at issue was in the range of lots with elevated levels of endotoxin, and that elevated endotoxin levels presented the same risks when implanted into animals as when implanted into humans. An **ACELL** employee spoke with the veterinarian, but did not inform her that the device used was sourced from a lot with elevated levels of endotoxin. **ACELL** ultimately closed the complaint, and provided the veterinarian with six free 100 mg vials of MicroMatrix. The complaint form does not document the possibility that elevated levels of endotoxin caused the event.

In March 2012, **ACELL** contracted with Qserve Group US, Inc. to verify **ACELL**'s compliance with FDA regulations. On May 17, 2012, Qserve's audit report found 11 high regulatory risk deficiencies in **ACELL**'s processes, including:

> inadequate investigations for complaints, medical device reporting, and failure investigations and root cause analyses for Corrective and Preventive Actions;
>
> inadequate supplier evaluation, risk management procedures, design history files, and production and process controls; and
>
> failure to validate the shelf life for Lyophilized Powder, sold as MicroMatrix; the master plan; and manufacturing processes.

Qserve made specific audit findings, including **ACELL**'s failure to establish an endotoxin level for Lyophilized Wound Dressing (Powder), sold as MicroMatrix; inability to track the batch and lot numbers of Surgical Mesh sheets used to manufacture Lyophilized Powder, sold as MicroMatrix; failure to investigate product and process nonconformities as root causes of patient complaints and to prevent recurrences; a regulatory opinion clearing PSMX Sheets for use in breast reconstruction without FDA clearance; and products sold as custom devices that did not qualify as custom devices and were not cleared by FDA. Qserve informed **ACELL** of the significant risk for FDA enforcement action, and recommended corrective actions.

During an inspection conducted by the FDA at **ACELL**'s Maryland headquarters in November and December 2012, FDA inspectors reviewed **ACELL**'s complaint history files and discovered that, in at least two instances, **ACELL** failed to furnish MDRs within 30 days after **ACELL** became aware of information reasonably suggesting that a device may have caused or contributed to a death or serious injury. The inspectors' findings related to cases involving **ACELL**'s endotoxin-contaminated PSMX Sheets that may have contributed to patient infections that necessitated surgical intervention. Following the inspection, on April 26, 2013, the FDA issued a Warning Letter to **ACELL**. The Warning Letter described several violations of the FDCA committed by **ACELL**, including **ACELL**'s failure to furnish the FDA with timely MDRs. The warning letter was closed on June 1, 2016.

SO STIPULATED:

Roann Nichols
Assistant United States Attorney

Patrick McBrayer
President and Chief Executive Officer
Defendant ACell, Inc.

Melissa Bayer Tearney, Esq.
Counsel for Defendant

ATTACHMENT C

COMPLIANCE PROGRAM AND CERTIFICATIONS

ACell, Inc. ("ACell" or "the company") agrees to the provisions set forth in this Attachment, which is incorporated by reference as part of the Plea Agreement (the "Agreement") between the Office of the United States Attorney for the District of Maryland and the United States Department of Justice, Consumer Protection Branch (collectively, the "United States" or the "Government") and ACell.

I. Compliance and Ethics Program

1. ACell will maintain a Compliance and Ethics Program that governs ACell's business operations. The purpose of the Compliance and Ethics Program is to (a) prevent, detect, and correct violations of law and company policy and procedures; (b) assure the continuation of compliance-related policies and procedures for business operations; (c) assure the continued development of training and other programs designed to educate employees regarding applicable policies, procedures, and standards; (d) conduct auditing and monitoring of the effectiveness of applicable policies, procedures, and standards; (e) assure that there is a mechanism for internal reporting of questionable or inappropriate activities to enable timely investigation and resolution; and (f) assure that appropriate corrective action is taken to prevent recurrence of misconduct.

2. The Compliance and Ethics Program will consist of a Chief Compliance Officer who reports to the Board of Directors of ACell and sits on the staff of the Chief Executive Officer of ACell, a Compliance Committee comprised of senior executives which meets at least four times a year, a comprehensive set of policies and procedures governing the conduct of its employees, a training program focused on the company's compliance policies and procedures, a hotline to allow employees to report potential violations of law or the company's compliance

policies and procedures, an anti-retaliation policy, and a monitoring and auditing program designed to deter and detect compliance issues. The Chief Compliance Officer is responsible for overseeing the administration and implementation of the Compliance and Ethics Program. The Chief Compliance Officer reports at least quarterly on the Compliance and Ethics Program to the Board of Directors. The Chief Compliance Officer has direct access to senior executives vested with the authority to direct and implement compliance-related changes in ACell if necessary. The Chief Compliance Officer has the authority to exercise independent judgment in assessing compliance-related matters. The Chief Compliance Officer has the authority to seek advice from outside legal counsel or other outside experts when appropriate. The Chief Compliance Officer is authorized to report issues of any kind directly to the Board of Directors of ACell (or a Committee thereof).

3. ACell will include and maintain compliance policies and procedures designed to prevent, detect, and correct violations of the Federal Food, Drug, and Cosmetic Act ("FDCA") regarding: (1) the documentation and reporting of medical device corrections, removals, and recalls; (2) the investigation, documentation, and reporting of medical device complaints; and (3) the marketing of medical devices.

II. Notice to Healthcare Providers and Entities

4. Within thirty (30) days after the entry of the guilty plea in this matter and for a period of one (1) year thereafter, ACell shall post in a prominent place on the main page of the healthcare professional section of its website a notice, dated and signed by the Chief Executive Officer of ACell, containing the language set forth below:

> As you may be aware, ACell recently entered into a civil, criminal, and administrative settlement with the United States and individual states in connection with ACell's promotion and sales of several of its products. This letter provides you with additional information

about the global settlement, explains ACell's commitments going forward, and provides you with access to information about those commitments.

ACell has agreed to plead guilty to a misdemeanor under the Federal Food, Drug and Cosmetic Act relating to its failure to properly implement a recall in 2012. In addition, ACell entered into a separate civil settlement relating to allegations that ACell engaged in improper sales and marketing practices. To resolve those allegations, ACell has agreed to pay approximately $15 million to federal and state health care programs. More information about this settlement may be found at the following: **[The notice shall include a link to the USAO, CPB, and ACell websites in the letter.]**

As part of the global settlement, ACell also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at http://oig.hhs.gov/fraud/cia/index.html. Under this agreement, ACell agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by ACell's representatives to ACell's Compliance organization or the FDA using the information set out below.

Please call ACell's Ethics and Integrity Helpline at 1-844-620-0004 or visit us at www.lighthouse-services.com/acell if you have questions about the settlement referenced above or to report any instances in which you believe that an ACell representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by an ACell Representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about ACell products to 1-844-620-0004 or visit us at www.lighthouse- services.com/acell.

5. The Chief Compliance Officer (or a designee) shall maintain a log (the "Log") of all calls and messages received by the Compliance and Ethics Program that report questionable practices by ACell employees, including issues or questions associated with ACell's policies, conduct, practices or procedures with respect to a Federal health care program or an FDA

requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. The Log shall include any such calls or messages in response to the notice above. The Log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. ACell shall produce the Log to the United States within ten (10) days of a written request for such production, for a period of three (3) years after the entry of the ACell guilty plea in this matter.

III. Certifications and Board Resolutions

6. ACell will conduct the reviews described in Paragraphs 7 through 9 below for each of three (3) Review Periods. The duration of each Review Period will be one (1) year, beginning with the first one-year period following the Effective Date of the Corporate Integrity Agreement to be executed between the Office of Inspector General for the Department of Health and Human Services and ACell. ACell will provide the certifications and resolutions described in Paragraphs 7 through 9 below to the Government within sixty days following the end of each of the Review Periods.

7. Following the end of each Review Period, the Chief Compliance Officer shall conduct a review of the Log described in Paragraph 5 above for the preceding Review Period. Based on his or her review, the Chief Compliance Officer shall submit to the Government a signed certification (the "Log Certification") (a) stating that, to the best of his or her knowledge, during the preceding Review Period, ACell maintained the Log pursuant to this Agreement; and (b) stating the total number of calls and messages received by the Compliance and Ethics Program through its disclosure program, including any such calls or messages made in response to the notice in Paragraph 4, and the number of those calls and messages for each month of the

preceding Review Period that relate to (1) the documentation and reporting of medical device corrections, removals, and recalls; (2) the investigation, documentation, and reporting of medical device complaints; and (3) the marketing of medical devices.

8. Following the end of each Review Period, the Chief Executive Officer of ACell shall conduct a review of the effectiveness of the Compliance and Ethics Program for the preceding Review Period. Based on his or her review, the President of ACell shall submit to the Government a signed certification stating that, to the best of his or her knowledge based on a reasonable inquiry, during the preceding Review Period, the Compliance and Ethics Program was effective in identifying and preventing violations of the FDCA. The certification shall summarize the review described above. If the President of ACell is unable to certify that the Compliance and Ethics Program was effective in preventing violations of the FDCA, he or she shall provide a detailed explanation of why the Compliance and Ethics Program was not effective, and will state the steps ACell is taking to ensure the effectiveness of the Compliance and Ethics program.

9. Following the end of each Review Period, the Board of Directors of ACell, or a designated Committee thereof (the "Board"), shall conduct a review of the effectiveness of the Compliance and Ethics Program for the preceding Review Period. This review shall include, but not be limited to, updates and reports by the Chief Compliance Officer and other personnel regarding compliance matters. The Board shall evaluate the effectiveness of the Compliance and Ethics Program, including, at a minimum, by receiving updates about the activities of the Compliance Committee and updates about the adoption and implementation of policies, procedures, and practices to ensure compliance with the FDCA. Based on its review, the Board

shall submit to the Government a resolution that summarizes its review and oversight as set forth above and that includes, at a minimum, the following language:

> The Board of Directors of ACell, Inc. (or a designated Committee of the board) has made a reasonable inquiry as described in Attachment C of the Plea Agreement with ACell into the operations of the Compliance and Ethics Program for the preceding Review Period, [insert date range], including the performance of the Chief Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, ACell has implemented an effective compliance program, as defined in the United States Sentencing Commission Guidelines Manual, Chapter 8: Sentencing of Organizations, to meet the requirements of the Federal Food, Drug, and Cosmetic Act, and as set forth in Attachment C to the Plea Agreement.

If the Board is unable to provide any part of this statement, it shall include in the resolution a written explanation of the reasons why it is unable to provide such a statement.

IV. Additional Reporting Obligations

10. Fifteen (15) days after the end of each calendar quarter (that is, by January 15 for the calendar quarter ending December 31, April 15 for the calendar quarter ending March 31, July 15 for the calendar quarter ending June 30, and October 15 for the calendar quarter ending September 30), excepting any calendar quarter that ends within sixty (60) days of the end of the third Review Period described in this Agreement, ACell shall submit a report to the Government in writing stating whether any Reportable Events have been determined to have occurred during the preceding calendar quarter, and providing updated information about Reportable Events that ACell determined to have occurred during any prior calendar quarter, as may be necessary in the reasonable determination of ACell or at the Government's request. A Reportable Event means anything that, after a reasonable opportunity to conduct an appropriate review or investigation of

the allegations, a reasonable person would consider to constitute: (a) a probable violation of FDCA requirements relating to the marketing or promotion of a medical device; (b) the initiation of a recall of a medical device; (c) the failure to report to the FDA a medical device correction or removal, as required by 21 U.S.C. § 360i(g); or (d) the failure to submit a medical device report (MDR) to the FDA, as required by 21 U.S.C. § 360i(a). A Reportable Event may be the result of an isolated event or a series of occurrences.

V. Filing of Certifications, Resolutions, and Reports

11. The certifications referenced above in Paragraphs 7 and 8 shall be sworn to under penalty of perjury and shall set forth that the representation contained therein may be provided to, relied upon, and material to the government of the United States, and that a knowing false statement could result in criminal or civil liability for the signatory. The certifications referenced above in Paragraphs 7 and 8, the resolutions referenced above in Paragraph 9, and the reports referenced above in Paragraph 10, should be sent to:

Chief, Criminal Division
U.S. Attorney's Office
District of Maryland
36 S. Charles St., 4th Floor
Baltimore, MD 21201

Director, Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044

VI. Breach of this Attachment

12. ACell recognizes that each of the terms in this Attachment constitutes a material term of this Attachment. As a contractual remedy, ACell and the United States agree that failure to comply with the obligations set forth in this Attachment may lead to the imposition of the

following monetary penalties (hereafter "Stipulated Penalties"), in accordance with the following provisions:

a. A Stipulated Penalty of $3,000 per day for each day ACell (1) fails to maintain a Compliance and Ethics Program as set forth in section I above; (2) fails to timely supply the certifications and board resolutions as set forth in Section III above; or (3) fails to timely supply the reports as set forth in Section IV above. With regard to the certifications, board resolutions, and reports, the Stipulated Penalty will begin to accrue on the first day after the date the document was due, subject to the provisions for extension of time for compliance and the opportunity to cure set forth below.

b. ACell may submit a timely written request for an extension of time to provide the certifications, resolutions, or reports required above. A written request is timely if it is received by the U.S. Attorney's Office for the District of Maryland and the Consumer Protection Branch, U.S. Department of Justice, at least five business days prior to the date by which the certification, resolution, or report is due. Timely requests for extension will not be unreasonably denied. If an extension of time is granted in writing, Stipulated Penalties shall not accrue until one day after ACell fails to meet the revised deadline. If not granted, Stipulated Penalties shall not begin to accrue until three business days after ACell receives the United States' written denial of such request or the original deadline, whichever is later.

c. Upon the United States' reasonable determination that ACell has failed to comply with any of the obligations described herein, the United States shall

notify ACell in writing of ACell's failure to comply and the United States' exercise of its contractual right to demand payment of the Stipulated Penalties (the "Demand Letter"). The Demand Letter shall set forth: (1) the provision(s) breached; (2) the date of the breach; (3) a description of the breach sufficient to permit ACell to cure (as described below); and (4) the amount of Stipulated Penalties claimed by the United States as of the date of the Demand Letter. Within fourteen (14) days after receipt of the Demand Letter, or such other period as the United States may agree in writing, ACell shall cure the breach to the United States' reasonable satisfaction ("Cure Period"). If ACell cures the breach within the Cure Period, no Stipulated Penalties shall be due. If ACell fails to cure the breach during the Cure Period, Stipulated Penalties calculated from the date of breach to the date of payment shall be immediately payable to the United States. The Stipulated Penalties shall be paid by electronic fund transfer according to wire instructions that will be provided by the United States. A joint reasonable determination by the United States Attorney's Office for the District of Maryland and the United States Department of Justice's Consumer Protection Branch as to whether ACell has cured any breach will be final and non-appealable. ACell agrees that the United States District Court for the District of Maryland shall have jurisdiction over any action to collect a penalty. If ACell fails to timely make a payment required by this Attachment, interest (at the rate specified in Title 28, United States Code, Section 1961) shall accrue on the unpaid balance through the date of payment.

13. The absence of a Demand Letter from the United States is not, and shall not be construed as, evidence of compliance with this Attachment, the FDCA, or any other applicable laws, policies, or procedures.

Unanimous Written Consent of the Board of Directors

April 16, 2019

The undersigned, being all of the directors of ACell, Inc., a Delaware corporation (the "Company"), do hereby take, pursuant to Section 141(f) of the General Corporation Laws of the State of Delaware, the following actions by written consent:

WHEREAS, the Company is entering into certain Settlement Agreements (the "State Settlement Agreements") with Maryland, Florida, and Wisconsin, and a certain Settlement Agreement (the "Federal Settlement Agreement") with the United States of America, acting through its Department of Justice, the United States Attorney's Office for the District of Maryland, the Office of Inspector General of the United States Department of Health and Human Services, the Defense Health Agency acting on behalf of the TRICARE program, the United States Department of Veteran Affairs, and the Relators identified therein, and a waiver of indictment (the "Waiver of Indictment") and a plea agreement with the United States Attorney's Office for the District of Maryland and the United States Department of Justice Consumer Protection Branch (the "Plea Agreement"), all of which are intended to resolve certain civil and criminal claims in consideration of payment by the Company of a total of fifteen million dollars ($15,000,000), plus interest, plus the Relator's attorneys' fees in the amount of two hundred and twenty-three thousand dollars ($223,000) (as so described, the "Settlement").

WHEREAS, in connection with the Settlement, the Company is entering into a Corporate Integrity Agreement (the "Corporate Integrity Agreement") with the Office of Inspector General of the United States Department of Health and Human Services to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and other Federal health care programs and the statutes, regulations and written directives of the Food and Drug Administration.

SETTLEMENT DOCUMENTS

NOW, THEREFORE, BE IT RESOLVED, that the Company be, and hereby is, authorized to enter into, execute and deliver the State Settlement Agreements, the Federal Settlement Agreement, the Corporate Integrity Agreement, the Waiver of Indictment and the Plea Agreement; and to comply with all other terms and conditions contained therein, on such terms and conditions set forth in the forms presented to the Company's Board of Directors (the "Board") herewith, with such additions and modifications as the Board deems, in its sole discretion, necessary or appropriate and in the best interests of the Company.

FURTHER RESOLVED, that the Board hereby acknowledges that the State Settlement Agreements, the Federal Settlement Agreement, the Corporate Integrity Agreement, the Waiver of Indictment and the Plea Agreement fully set forth the agreements made between the Company and the United States, and further acknowledges that no additional promises or representations have been made to the Company by any officials of the United States in connection with the disposition of the Settlement.

FURTHER RESOLVED, that the Board hereby acknowledges that it has reviewed the Information and the Plea Agreement and has consulted with legal counsel in connection with the matter.

GENERAL AUTHORIZATIONS

FURTHER RESOLVED, that any and all acts, transactions, agreements or certificates previously signed by or on behalf of the Company in furtherance of the foregoing be, and hereby are, in all respects approved and ratified as the true acts and deeds of the Company with the same force and effect as if such act, transaction, agreement or certificate had been specifically authorized in advance by resolution by the Board,

FURTHER RESOLVED, that Patrick A. McBrayer, President and Chief Executive Officer of the Company be, and is, authorized and directed in the name and on behalf of the Company, to execute and deliver the State Settlement Agreements, the Federal Settlement Agreement, the Corporate Integrity Agreement, the Waiver of Indictment and the Plea Agreement and any and all other agreements, instruments, documents and certificates, and to take any and all actions which such members may deem necessary, appropriate or desirable in connection with or in furtherance of the actions contemplated by all of the foregoing resolutions, and that the execution and delivery of such agreements, instruments, documents and certificates and the taking of such actions, by such members shall be conclusive evidence of such determination and approval of the Board,

FURTHER RESOLVED, that an officer of the Company be, and hereby is, authorized to sign a letter directing ACell, Inc., to make payment in accordance with the terms of the State Settlement Agreements, the Federal Settlement Agreement, and the Plea Agreement.

FURTHER RESOLVED, that this Consent may be executed in one or more counterparts, all of which together shall constitute one and the same Consent.

Such resolutions have not been amended, modified, rescinded or revoked and remain in full force and effect on the date hereof.

[Signature Page Follows]

The undersigned further direct that this consent shall take effect immediately as of the date first above written and shall be filed in the minute book of the Corporation with the minutes of the meetings of the Board of Directors.

Kyle Kerbawy

Louis Baldino

David Anderson

Patrick McBrayer

Sally Maher

The undersigned further direct that this consent shall take effect immediately as of the date first above written and shall be filed in the minute book of the Corporation with the minutes of the meetings of the Board of Directors.

Kyle Kerbawy

Skip Baldino

Louis Baldino

David Anderson

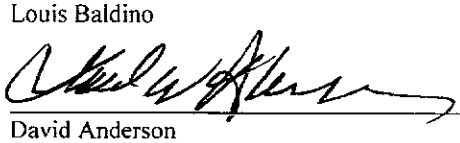
Patrick McBrayer

Sally Maher

The undersigned further direct that this consent shall take effect immediately as of the date first above written and shall be filed in the minute book of the Corporation with the minutes of the meetings of the Board of Directors.

Kyle Kerbawy

Louis Baldino



David Anderson

Patrick McBrayer

Sally Maher

The undersigned further direct that this consent shall take effect immediately as of the date first above written and shall be filed in the minute book of the Corporation with the minutes of the meetings of the Board of Directors.

Kyle Kerbawy

Louis Baldino

David Anderson

Patrick McBrayer

Sally Maher

The undersigned further direct that this consent shall take effect immediately as of the date first above written and shall be filed in the minute book of the Corporation with the minutes of the meetings of the Board of Directors.

Kyle Kerbawy

Louis Baldino

David Anderson

Patrick McBrayer

Sally Maher Digitally signed by Sally Maher
Date: 2019.04.16 13:10:56 -04'00'

Sally Maher

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS), the Defense Health Agency (DHA), acting on behalf of the TRICARE Program, and the United States Department of Veteran Affairs (VA) (collectively, the "United States"), ACell, Inc. (ACell), John Murtaugh, and Ali Mahdavi (collectively the "Relators") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. ACell is a manufacturer of medical devices organized under the laws of the state of Delaware with its principal place of business in Maryland. ACell develops, manufactures, processes, packages, sells, markets, and distributes medical devices derived from porcine urinary bladder material, including devices approved for internal surgical implantation and devices approved only as topical wound dressings.

B. On June 21, 2013, John Murtaugh filed a *qui tam* action in the United States District Court for the District of Maryland captioned *United States ex rel. John Murtaugh v. ACell, Inc.*, Action No. ELH-13-1820, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b). On September 9, 2016, Ali Mahdavi filed a *qui tam* action in the United States District Court for the Eastern District of Wisconsin captioned *United States ex rel. Ali Mahdavi, M.D. v. ACell, Inc., et al.*, Action No. SEALED pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b). Collectively, these actions are referred to as the "Civil Actions."

C. ACell has entered or will be entering into separate settlement agreements, described in Paragraph 1.b., below (hereinafter referred to as the "Medicaid State Settlement Agreements"), with Maryland, Florida and Wisconsin in settlement of the Covered Conduct. States with which ACell executes a Medicaid State Settlement Agreement in the form to which ACell and that State have agreed, or in a form otherwise agreed to by ACell and an individual State, shall be defined as the "Medicaid Participating States."

D. The United States contends that ACell submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 ("Medicare"); the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid"); the TRICARE Program, 10 U.S.C. §§ 1071-1110b ("TRICARE"); and the Department of Veterans Affairs, Veterans Health Administration, 38 U.S.C. Chapter 17.

E. The United States contends that it has certain civil claims against ACell arising from certain ACell practices during the period from January 1, 2009 through October 20, 2014 as follows:

> (1) The FDA cleared ACell's MicroMatrix powder in June 2006 pursuant to the FDA's 510(k) program and assigned number K060888. The FDA clearance letter accompanying 510(k) number K060888 stated that MicroMatrix was indicated for "the management of topical wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), and draining wounds."
>
> The United States contends that beginning in 2011, ACell marketed its MicroMatrix powder products for non-topical or internal uses, such as fistula and hernia repairs, breast reconstructive surgeries, open abdomen surgeries, and internal injections of MicroMatrix in hair restoration and orthopedic procedures. ACell's management instructed its sales force that every surgical procedure presented an opportunity to sell MicroMatrix and directed that sales representatives encourage doctors to "powder everything." The United States

further contends that ACell's promotion was false and misleading because, at the direction of management, ACell sales representatives stated to physicians that the use of powder non-topically and internally was safe and effective, when the sales representatives knew that no such clinical data existed. Moreover, these internal uses of the product fell outside the FDA clearance.

(2) The United States contends that beginning in March 2012, ACell provided coding recommendations to hospitals and long term care hospitals ("LTCHs") related to the use of ACell devices in the in-patient setting that were incorrect and operated to improperly inflate reimbursement from Medicare. ACell referred to this strategy as "Bump the DRG." These codes, including code 86.65 (heterograft to skin), did not accurately reflect the treatment rendered, which would in turn lead to increased sales for ACell in the hospital and LTCH setting.

The United States further contends that ACell created various "cheat sheets" for distribution to hospitals and LTCHs that provided specific guidance to hospitals and LTCHs on which inpatient procedure codes to use with ACell devices in order to improperly increase the amount of reimbursement.

In December 2012 and again in November 2013, ACell consulted with two separate coding consultants about the propriety of adding procedure code 86.65 when a health care provider used ACell's product in the in-patient setting. Both consultants informed ACell that the use of 86.65 was not appropriate because ACell's products were not a skin graft. Nevertheless, despite the advice from its consultants, ACell continued to give improper DRG coding advice to hospitals and LTCHs.

(3) The United States contends that ACell induced prescribers to order ACell products by providing improper inducements, including entertainment and speaker programs payments, designed to encourage orders from the health care professionals who were the recipients of those inducements, and free product. ACell classified the free product as "educational gifts" to physicians and hospitals.

The conduct described above is referred to below as the "Covered Conduct."

F. Except to the extent admitted in ACell's guilty plea, this Settlement Agreement is neither an admission of liability by ACell nor a concession by the United States that its claims are not well founded. Except to the extent admitted in ACell's guilty plea, ACell expressly denies the allegations of the United States and the Relators set forth in the Civil Actions.

G. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators' reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. ACell shall pay to the United States and the Medicaid Participating States collectively Twelve Million Dollars ($12,000,000) and interest on the Settlement Amount at a rate of 2.875% from September 1, 2018 (Settlement Amount), which constitutes restitution to the United States. On the Effective Date of this Agreement, this sum shall constitute a debt due and immediately owing to the United States. The Settlement Amount is to be paid to the United States and the Medicaid Participating States as follows:

a. $11,830,020 (plus accrued interest) shall be payable to the United States (Federal Settlement Amount) pursuant to instructions from the Civil Division of the United States Department of Justice.

b. $169,980 (plus accrued interest) shall be payable to the Medicaid Participating States (State Settlement Amount) pursuant to instructions from the State Team.

c. The initial payment of Five-Hundred Thousand Dollars ($500,000), plus accrued interest at the rate of 2.875% accrued since September 1, 2018 on the Settlement Amount, to the United States shall be paid no later than seven (7) days after (i) this Agreement is fully executed by the Parties and delivered to ACell's attorneys, or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea as to ACell and imposes the agreed upon sentence, whichever occurs later.

d. ACell shall pay the balance of the Federal Settlement Amount, plus interest at the rate of 2.875%, in quarterly installment payments over the period of five years according to the payment schedule attached hereto as Attachment A.

e. In the event ACell is sold or merged or a significant amount of assets of ACell is sold, merged, or transferred into another non-affiliated entity, then ACell shall promptly notify the United States, and all remaining payments owed pursuant to the Settlement Agreement shall be accelerated and become due and payable within fifteen (15) days of such transaction.

f. The entire balance of the Settlement Amount, or any portion thereof, may be prepaid without penalty. If ACell elects to pre-pay the Settlement Amount or any portion thereof, interest shall be accrued through the date on which ACell makes said pre-payment.

g. If ACell's agreed-upon guilty plea pursuant to Fed. R. Crim. P. 11 in the matter of *United States v. ACell, Inc.*, Criminal Action No. [to be assigned] is not accepted by the Court or the Court does not impose the agreed-upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or ACell. If either the United States or ACell exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within ten (10) business days of the Court's order, the Parties will not object and this Agreement will be rescinded.

2. In the event that ACell fails to pay the Settlement Amount as provided in Paragraph 1 or any of the installment payments noted in Paragraph 1.d., within ten (10) business days of the date upon which each such payment is due, ACell shall be in Default of its payment obligations ("Default"). In the event of Default, the United States will provide a written Notice of Default to ACell, and ACell shall have an opportunity to cure such Default within ten (10) business days from the date of receipt of the Notice of Default ("Cure Period"). Notice of

Default will be delivered to Patrick A. McBrayer, President and CEO, ACell, Inc., 6640 Eli Whitney Drive, Suite 200, Columbia, MD 21046. If ACell fails to cure the Default within the Cure Period as described in this Paragraph ("Uncured Default"), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on ACell's unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Default, on the remaining unpaid total. The United States, at its sole option, may: (a) offset the remaining unpaid balance from any amounts due and owing to ACell by any department, agency, or agent of the United States at the time of Default; (b) collect the entire unpaid balance of the Settlement Amount, plus interest, including 12% interest from the date of Default, and all other amounts due upon the event of Default as specified in this paragraph; (c) file a civil action for the Covered Conduct; or (d) exercise any other rights granted by law or in equity, including referral of this matter for private collection. In the event a complaint is filed pursuant to subsection (c) of this paragraph, ACell agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories to the allegations in the complaint, except to the extent such defenses were available to ACell on June 21, 2013. ACell agrees not to contest any consent judgment, offset, recoupment and/or collection action undertaken by the United States pursuant to this paragraph, either administratively or in any state or federal court. ACell shall pay to the United States all reasonable costs of collection and enforcement under this paragraph, including attorneys' fees and expenses. ACell shall upon execution of this Settlement Agreement enter into a Consent Judgment which at the United States' sole discretion can be filed in the United States District Court for the District of Maryland in the event of an Uncured Default.

3. In the event of an Uncured Default, as defined in Paragraph 2, above, the OIG-HHS may exclude ACell from participating in all Federal health care programs until ACell pays the Settlement Amount and reasonable costs as set forth in Paragraph 1, above. The OIG-HHS will provide written notice of any such exclusion to ACell. ACell waives any further notice of the exclusion under 42 U.S.C. §1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion ACell wishes to apply for reinstatement, ACell must submit a written request for reinstatement to the OIG-HHS in accordance with the provision of 42 C.F.R. §§ 1001.3001-.3005. ACell will not be reinstated unless and until the OIG-HHS approves such request for reinstatement.

4. Conditioned upon the United States receiving the Settlement Amount payments from ACell according to the schedule in Paragraph 1, the United States agrees that it shall pay to Relator Murtaugh by electronic funds transfer 20% percent of each such payment received under the civil Settlement Agreement as soon as feasible after receipt of the payment. No other payments are due to any another person or relator.

5. ACell agrees to pay Relators and Relators' counsel $222,500 in full satisfaction of their claims for expenses, attorneys' fees, and costs incurred in connection with the Civil Actions under 31 U.S.C. § 3730(d), by electronic funds transfer pursuant to agreements between ACell and Relators and Relators' attorneys. No additional attorneys' fees and costs shall be paid or claimed by Relators or their counsel.

6. Subject to the exceptions in Paragraph 10 (concerning excluded claims) below, and conditioned upon ACell's full payment of the Settlement Amount and subject to Paragraph 24, below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date

of this Agreement or any payment made under this Agreement), the United States releases ACell, together with its current and former parent corporations, current and former direct and indirect subsidiaries, current and former brother or sister corporations, and the predecessors, successors, transferees, and assigns of any of them (the "ACell Released Parties") from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any statutory provision creating a cause of action for civil damages or civil penalties for which the Civil Division of the Department of Justice has actual or present authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I, 0.45(d); or the common law theories of payment by mistake, unjust enrichment, and fraud.

7. Subject to the exceptions in Paragraph 10 below, and conditioned upon ACell's full payment of the Settlement Amount and subject to Paragraph 24, below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, or any other person or entity acting on their behalf or asserting their rights, fully and finally release, waive and forever discharge the ACell Released Parties and all of their past and present parent corporations, successors, assigns, and each and all of their current and former directors, officers, shareholders, attorneys, contractors, agents and employees, individually and collectively, from any civil monetary claim the Relators have on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

8. In consideration of the obligations of ACell in this Agreement and the Corporate Integrity Agreement (CIA), entered into between the OIG-HHS and ACell, and conditioned upon ACell's full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against ACell under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 10 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude ACell from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 10, below.

9. In consideration of the obligations of ACell set forth in this Agreement, and conditioned upon ACell's full payment of the Settlement Amount, DHA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against ACell under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 10 (concerning excluded claims), below. DHA expressly reserves authority to exclude ACell from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii) (mandatory exclusion), based upon the Covered Conduct. Nothing in this Paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 10, below.

10. Notwithstanding the releases given in paragraphs 6-9 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

h. Any liability for failure to deliver goods or services due; or

i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

11. Relators and their heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B), and expressly waive the opportunity for a hearing on any objection to this Agreement. Conditioned upon Relator Murtaugh's receipt of the payments described in Paragraph 4, Relators and their heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge

the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Actions or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Actions.

12. Relators, for themselves, and for their heirs, successors, attorneys, agents, and assigns, or any other person or entity acting on their behalf or asserting their rights, fully and finally release, waive and forever discharge, the ACell Released Parties and all of their past and present parent corporations, successors, assigns, and each and all of their current and former directors, officers, shareholders, attorneys, contractors, agents, and employees, individually and collectively, from any and all civil monetary claims and any liability, claims, allegations, demands, claims for relief, rights, actions or causes of action of every nature whatsoever, suits, debts, obligations, liabilities, losses, damages (including treble damages and any civil penalties), punitive damages, costs and expenses of any kind, character or nature whatsoever, existing as of the Effective Date of this Agreement, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or under common law that Relators or their heirs, successors, agents, or assigns would have standing to bring, whether or not related to or arising from the Civil Actions, or from any past activities and actions of the ACell Released Parties, including without limitation, claims relating to or arising from the filing of the Civil Actions, not limited to those Relators advanced or could have advanced in the Civil Actions, and claims under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs. The foregoing release does not affect the separate agreements between ACell, Relators and Relators' counsel that are referenced above in Paragraph 5. Subject to this exception, this Paragraph is intended to be interpreted as a general release on behalf of Relators, who warrant

and represent that they have not assigned or transferred any of their claims to any person, entity, or thing.

13. ACell has provided sworn financial disclosure statements (Financial Statements) to the United States and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Agreement. ACell warrants that the Financial Statements are complete, accurate, and current as of the date of execution of this Agreement. If the United States learns of asset(s) in which ACell had an interest at the time of this Agreement that were not disclosed in the Financial Statements, or if the United States learns of any misrepresentation by ACell on, or in connection with, the Financial Statements, and if such nondisclosure or misrepresentation changes the estimated net worth set forth in the Financial Statements by $1,000,000 or more, the United States may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct, or (b) let the Agreement stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth of ACell previously undisclosed. ACell agrees not to contest any collection action undertaken by the United States pursuant to this provision, and immediately to pay the United States all reasonable costs incurred in such an action, including attorneys' fees and expenses.

14. In the event that the United States, pursuant to Paragraph 13 (concerning disclosure of assets), above, opts to rescind this Agreement, ACell agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within thirty (30) calendar days of written notification to ACell that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on June 21, 2013.

15. ACell waives and shall not assert any defenses ACell may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

16. ACell fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that ACell has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

17. ACell fully and finally releases the Relators and their heirs, assigns, attorneys, and agents from any claims, including any and all claims, claims for relief, actions, rights, causes of actions, suits, debts, obligations, liabilities, demands, losses damages, punitive damages, costs and expenses of any kind, character or nature whatsoever existing as of the Effective Date of this Agreement, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, or otherwise that they, their heirs, successors, agents and assigns otherwise have standing to bring, whether or not related to the Civil Actions. This Paragraph is intended to be interpreted as a general release, and the ACell Released Parties warrant and represent that they have not assigned or transferred any of their claims to any person, entity, or thing. ACell reserves any defenses or claims as to Relators' unresolved claims in the Civil Actions or Relators' counsel's claims for reasonable attorneys' fees, expenses, and costs resulting from the Civil Actions or other action brought by Relators against ACell.

18. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier), TRICARE carrier or payer, or any state payer, related to the Covered Conduct; and ACell agrees not to resubmit to any Medicare contractor or TRICARE carrier or payer or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

19. ACell agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of ACell, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement and any related plea agreement;

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(3) ACell's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);

(4) the negotiation and performance of this Agreement and any Plea Agreement;

(5) the payment ACell makes to the United States pursuant to this Agreement and any payments that ACell may make to Relators, including costs and attorneys' fees; and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, and the TRICARE Program, (hereinafter referred to as Unallowable Costs). However, nothing in paragraph 19.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to ACell.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by ACell, and ACell shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by ACell or any of its subsidiaries or affiliates to the Medicare, Medicaid, or TRICARE Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: ACell further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including,

but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by ACell or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. ACell agrees that the United States, at a minimum, shall be entitled to recoup from ACell any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by ACell or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on ACell or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine ACell's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

20. ACell agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, ACell shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. ACell further agrees to furnish to the United States, upon

request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

21. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 22 (waiver for beneficiaries paragraph), below.

22. ACell agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

23. ACell warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and expects to remain solvent following payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to ACell, within the meaning of 11 U.S.C. § 547(c)(1), and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which ACell was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

24. If within 91 days of the Effective Date of this Agreement or of any payment made under this Agreement, ACell commences, or a third party commences, any case, proceeding, or

other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of ACell's debts, or seeking to adjudicate ACell as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for ACell or for all or any substantial part of ACell's assets, ACell agrees as follows:

a. ACell's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and ACell shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) ACell's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) ACell was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to ACell.

b. If ACell's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against ACell for the claims that would otherwise be covered by the releases provided in Paragraphs 6-9, above. ACell agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceedings described in the first clause of this Paragraph, and ACell shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) ACell shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or

administrative claims, actions, or proceeding that are brought by the United States within thirty (30) calendar days of written notification to ACell that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on June 21, 2013; and (iii) the United States has a valid claim against ACell in the amount of $54,805,185 and the United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

c. ACell acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

25. Upon receipt of the initial payment described in Paragraph 1.c., above, the Parties shall promptly sign and file:

a. In Action No. ELH-13-1820 (D. Md.), a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(2). The Stipulation of Dismissal shall be with prejudice as to the United States' and Relator's claims against ACell as to the Covered Conduct and shall be without prejudice to the United States and with prejudice to the Relator as to all other claims against ACell.

b. In Action No. SEALED (E.D. Wisc.), a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(2) that will dismiss ACell. The Stipulation of Dismissal shall be with prejudice as to the United States' and Relator's claims against ACell as to the Covered Conduct and shall be without prejudice to the United States and with prejudice to the Relator as to all other claims against ACell.

26. Except as set forth in Paragraph 5, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

27. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

28. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Maryland. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

29. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

30. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

31. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

32. This Agreement is binding on ACell's successors, transferees, heirs, and assigns.

33. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.

34. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

35. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 5/14/19 BY: _____

THOMAS CORCORAN
Assistant United States Attorney
District of Maryland

DATED: 5/13/2019 BY: _____

MICHAEL D. GRANSTON
JAMIE A. YAVELBERG
NATALIE A. WAITES
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____ BY: _____

LEIGH A. BRADLEY
General Counsel
Defense Health Agency
United States Department of Defense

THE UNITED STATES OF AMERICA

DATED: _____ BY: _____
THOMAS CORCORAN
Assistant United States Attorney
District of Maryland

DATED: _____ BY: _____
MICHAEL D. GRANSTON
JAMIE A. YAVELBERG
NATALIE A. WAITES
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 04/16/2019 BY: Lisa M Re
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____ BY: _____
LEIGH A. BRADLEY
General Counsel
Defense Health Agency
United States Department of Defense

THE UNITED STATES OF AMERICA

DATED: _____ BY: _____
THOMAS CORCORAN
Assistant United States Attorney
District of Maryland

DATED: _____ BY: _____
MICHAEL D. GRANSTON
JAMIE A. YAVELBERG
NATALIE A. WAITES
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: April 24, 2019 BY: _____
LEIGH A. BRADLEY
General Counsel
Defense Health Agency
United States Department of Defense

DEFENDANT

DATED: 5/9/19 BY: _____

Patrick McBrayer
President and Chief Executive Officer
ACell, Inc.

DATED: 5/9/19 BY: _____

Melissa Bayer Tearney
Choate, Hall & Stewart, LLP
Counsel for ACell, Inc.

RELATORS

DATED: 04/15/2019 BY: _____
John Murtaugh

DATED: 4/15/2019 BY: _____
James Young, Esq.
Morgan and Morgan
Counsel for John Murtaugh

DATED: _____ BY: _____
Ali Mahdavi

DATED: _____ BY: _____
Nola Cross, Esq.
Cross Law Firm
Counsel for Ali Mahdavi

RELATORS

DATED: _____ BY: _____
John Murtaugh

DATED: _____ BY: _____
James Young, Esq.
Morgan and Morgan
Counsel for John Murtaugh

DATED: 05/04/2019 BY: Ali Mahdavi
Ali Mahdavi

DATED: 5/6/2019 BY: _____
Nola J. Hitchcock Cross, Esq.
Cross Law Firm
Counsel for Ali Mahdavi

ACell, Inc.

Civil Federal

Quarter	Payment	2.875% Interest	Principal	Balance
				$11,830,020.00
6/12/2019	$763,704.11	$263,704.11	$500,000.00	$11,330,020.00
9/12/2019	$480,284.52	$81,434.52	$398,850.00	$10,931,170.00
12/12/2019	$477,417.78	$78,567.78	$398,850.00	$10,532,320.00
3/12/2020	$474,551.05	$75,701.05	$398,850.00	$10,133,470.00
6/12/2020	$471,684.32	$72,834.32	$398,850.00	$9,734,620.00
9/12/2020	$678,400.30	$69,967.58	$608,432.72	$9,126,187.28
12/12/2020	$674,027.19	$65,594.47	$608,432.72	$8,517,754.56
3/12/2021	$669,654.08	$61,221.36	$608,432.72	$7,909,321.84
6/12/2021	$665,280.97	$56,848.25	$608,432.72	$7,300,889.12
9/12/2021	$660,907.86	$52,475.14	$608,432.72	$6,692,456.40
12/12/2021	$656,534.75	$48,102.03	$608,432.72	$6,084,023.68
3/12/2022	$652,161.64	$43,728.92	$608,432.72	$5,475,590.96
6/12/2022	$647,788.53	$39,355.81	$608,432.72	$4,867,158.24
9/12/2022	$643,415.42	$34,982.70	$608,432.72	$4,258,725.52
12/12/2022	$639,042.31	$30,609.59	$608,432.72	$3,650,292.80
3/12/2023	$634,669.20	$26,236.48	$608,432.72	$3,041,860.08
6/12/2023	$630,296.09	$21,863.37	$608,432.72	$2,433,427.36
9/12/2023	$625,922.98	$17,490.26	$608,432.72	$1,824,994.64
12/12/2023	$621,549.87	$13,117.15	$608,432.72	$1,216,561.92
3/12/2024	$617,176.76	$8,744.04	$608,432.72	$608,129.20
6/12/2024	$612,500.13	$4,370.93	$608,129.20	$0.00
	$12,996,969.86	**$1,166,949.86**	**$11,830,020.00**	

Note:

1. The Initial Payment includes handshake interest from 9/1/2018 through 6/11/2019 (283 days).

Attachment A